



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-1102]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Tuberculosis Data from Panel Physicians to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 26, 2021 to obtain comments from the public and affected agencies. CDC received one non-substantive comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Tuberculosis Data from Panel Physicians (OMB Control No. 0920-1102, Exp. 9/30/2021) - Revision - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), Immigrant, Refugee, and Migrant Health Branch (IRMH), requests approval for a Revision to an approved information collection. The respondents are U.S. panel physicians. Panel physicians are medically trained, licensed, and experienced medical doctors practicing overseas who are appointed by the local U.S. Embassy or Consulate General to perform medical examinations for prospective immigrants to the United States. More than 760 panel physicians perform overseas pre-departure medical examinations at 336 panel sites, in accordance with requirements, referred to as *Technical Instructions*, provided by the Centers for Disease Control and Prevention's Division of Global Migration and Quarantine, Quality Assessment Program (QAP). The QAP program is housed in the Immigrant, Refugee, and Migrant Health Branch (IRMH). The role of QAP is to assist and guide panel physicians in the implementation of the *Technical Instructions*; evaluate

the quality of the overseas medical examination for U.S.-bound immigrants and refugees; assess potential panel physician sites; and provide recommendations to the U.S. Department of State in matters of immigrant medical screening.

To achieve DGMQ's mission, IRMH works with domestic and international programs to improve the health of U.S.-bound immigrants and refugees to protect the U.S. public by preventing the importation of infectious disease. These goals are accomplished through IRMH's oversight of medical exams required for all U.S. - bound immigrants and refugees who seek permanent residence in the U.S. IRMH is responsible for assisting and training the international panel physicians with the implementation of medical exam *Technical Instructions*. CDC's *Technical Instructions* are detailed requirements and national policies regarding the medical screening and treatment of all U.S.-bound immigrants and refugees.

Screening for tuberculosis (TB) is a particularly important component of the immigration medical exam and allows panel physicians to diagnose active TB disease prior to arrival in the United States. As part of the *Technical Instructions* requirements, panel physicians perform chest x-rays and laboratory tests that aid in the identification of tuberculosis infection (Class B1 applicants) and diagnosis of active tuberculosis disease (Class A, inadmissible applicants). CDC uses these classifications to report new immigrant and refugee arrivals with a higher risk of developing TB disease to U.S.

state and local health departments for further follow-up. Some information that panel physicians collect as part of the medical exam is not reported on the standard Department of State forms (DS-forms), thereby preventing CDC from evaluating TB trends in globally mobile populations and monitoring program effectiveness.

In 2007, CDC revised the *Tuberculosis Technical Instructions* to include several new requirements for *Mycobacteria tuberculosis* (MTB) testing and treatment. Important changes included the requirements for: 1) sputum cultures in addition to sputum smears; 2) tuberculin skin tests or interferon gamma release assays (beginning in 2009) for certain children aged 2-14 years examined in countries where the World Health Organization estimated TB incidence is ≥ 20 per 100,000 persons; 3) drug-susceptibility testing of positive isolates; and 4) treatment being delivered as directly observed therapy (DOT) throughout the entire course.

Since implementation of these new *Culture and Directly Observed Therapy TB Technical Instructions* (CDOT TB TI), overseas TB case detection has increased by an estimated 60% and allowed U.S. public health programs to save millions of dollars annually. Overseas TB screening data (referred to by DGMQ as 'TB Indicator data') is critical to support the continued analysis of these trends and the monitoring of TB control efforts in the U.S.

CDC requests this data collection approval for three years. This Revision includes a decrease in respondents from 336 to 333, and a decrease in the requested number of burden hours from 1,008 hours to 999. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

| Type of Respondents | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) |
|--------------------------------|-------------------------------|-----------------------|------------------------------------|--|
| International Panel Physicians | TB Indicators REDCap web form | 333 | 1 | 3 |

Jeffrey M. Zirger,
Lead,
Information Collection Review Office,
Office of Scientific Integrity,
Office of Science,
Centers for Disease Control and Prevention.
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